

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

jc518 U 09/283596 PTO  
04/01/90

15 TRANSMITTAL LETTER ACCOMPANYING  
INFORMATION SUBMISSION PURSUANT TO 37 CFR §1.56 AND MPEP §724

Assistant Commissioner of Patents  
Washington, D.C. 20231

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Dear Sir:

**TRADE SECRET MATERIAL NOT OPEN TO PUBLIC.**

**TO BE OPENED ONLY BY EXAMINER OR OTHER AUTHORIZED PATENT  
AND TRADEMARK OFFICE EMPLOYEE**

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Respectfully submitted

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: S. Carpentier, et al. ) Group Art Unit: Unknown  
Application No.: Unknown ) ) Examiner: Unknown  
Filing Date: Herewith ) )  
For: APPARATUSES FOR TREATING ) )  
BIOLOGICAL TISSUE TO ) )  
MITIGATE CALCIFICATION ) )

jc518 U.S. PTO  
09/28/96  
04/01/99  


Assistant Commissioner of Patents  
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

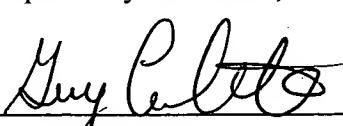
Pursuant to the duty of disclosure set forth under 37 CFR §§ 1.56, 1.97(c), and 1.98, Applicants enclose the attached form PTO-1449. This submission is prior to receipt of a first Office Action on the merits and thus, pursuant to 37 CFR § 1.97(b)(3), no fee is believed due.

Pursuant to 37 CFR § 1.98(d), copies of the patents listed on the Form PTO-1449 are not provided as they were of record in parent case S/N 08/874,180. Applicants will, of course, provide copies if examiner requires.

The material submitted pursuant to MPEP §724 is provided, along with a Petition to expunge.

Respectfully submitted,

Date: 3/31/99

  
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INFORMATION SUBMISSION PURSUANT TO 37 CFR §1.56 AND MPEP §724

Dear Sir:

This is to notify the Examiner in the above-referenced case of certain pre-filing activities of the Assignee which may be material under Rule 56. The activities comprise steps in tissue processing which are considered TRADE SECRETS.

For at least eight years the Edwards Cardiovascular division (now Heart Valve Therapy division) of Baxter International (the Assignee) has been processing fresh pericardial tissue for use in the manufacture and sale of bioprosthetic heart valves in the following way.

1. Trim fresh pericardial sac, then
2. Place individual pieces of fresh tissue in a container of glutaraldehyde, then
3. Shake the container in step 2 for 30 minutes, then
4. Remove the individual pieces of tissue from the container, then
5. Stack the individual pieces of tissue, then
6. Store the stacked pieces of tissue in solution of glutaraldehyde for 14 days.

Application Serial No.: Unknown  
Filing Date: Herewith

After step 6, the individual pieces of trimmed tissue are subjected to a sterilization treatment and are then cut into leaflets and assembled into tissue valve.

The shaking of step 3 is for the purpose of stirring the solution and removing areas depleted of glutaraldehyde. The tissue pieces are thus surface-exposed to glutaraldehyde prior to steps 5 and 6. No heat is applied to the solutions in any of steps 1-6.

Respectfully submitted,

Gary Cutts

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